

REMARKS

Interview with Examiner Phyllis Spivack

Applicants wish to thank Examiner Spivack for her courtesy and cooperation during the interview conducted on May 15, 2006.

During the above-noted interview, Applicants' representative discussed 1) providing a 1.132 declaration to remove the reference cited by the Examiner (Li, *et al.*) as a 102(a) prior art reference, 2) limiting the pending independent claims to "delaying labor" instead of "preventing and delaying labor" and, 3) what steps would need to be taken to remove the pending 112, first paragraph rejection of Claims 1 – 11.

The Applicants' representative stated that a properly executed 1.132 declaration would be provided to overcome the pending 102(a) rejection.

The Applicants' representative agreed to amend the pending independent claims to remove references to "preventing labor."

The Applicants' representative discussed with Examiner Spivack how to overcome the pending 112, first paragraph rejection. Examiner Spivack states in the pending Office Action "the claims are directed to the prevention of delaying of preterm uterine contractions in a pregnant mammal comprising administering a compound that inhibits kinase activity such that a decrease in the levels of both phosphorylated ERK and phosphorylated caldesmon in the pregnant mammal is achieved. The specification provides support for delaying preterm uterine contractions comprising administering the single compound designated U0126." The Applicants respectfully disagree with the Examiner.

Examiner Spivack suggested amending the claims to limit them to kinase inhibitor U0126. Examiner Spivack also stated that if the Applicant could show a commonality of structure between U0126 and other kinase inhibitors or the applicability of other kinase inhibitors for the same usage than a claim citing Markush group to the identified kinase inhibitors may be considered allowable. In this regard, the Applicants provide a reference showing an applicability of other known kinase inhibitors to methods of the present invention. It was known at the time of the present invention that two other kinase inhibitors (PD98059 and PD184532) were known to have the same mechanism of action as U0126.

Taken together, it seems very likely that PD98059, U0126 and PD184532 act as allosteric inhibitors: they bind outside the ATP- and ERK1/2-binding sites on MEK1/2 and the modification of the three-dimensional structure of MEK1/2 renders it not phosphorylatable by upstream kinases." Kohno and Pouyssegur, *Prog. in Cell Cycle Res.* 5:219-224, Jan. 1, 2003. p222, column 1, last paragraph.

In view of this prior art reference and solely in order to advance the Applicants' business interests while in no way acquiescing to the Examiner's arguments and while preserving the right to prosecute similar or identical un amended claims in the future, the Applicants have amended Claims 1 and 5 to limit the claimed invention to the three kinase inhibitors PD98059, U0126 and PD184532. The Applicants believe that said amendment now removes the 112, first paragraph rejection and places the claims in position for allowance.

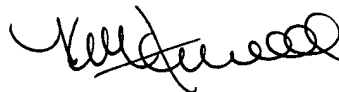
Claims 1-11 are not Anticipated Under 35 USC 102(a)

Claims 1-11 have been rejected under USC § 102(a) as being anticipated by Li, *et al.* The cited reference is a publication by the Inventors less than one year prior to the filing date of the present application. The Applicants have filed (attached hereto) a declaration under 37 CFR 1.132 establishing that the cited article is describing the Applicants' own work and the persons listed other than the Applicants (S. Malek and H-D Je) were merely working under the direction of the Applicants. It is respectfully submitted that the entry of the executed Declaration will overcome the rejection under 35 USC 102(a).

Summary

In light of the above amendment and remarks, reconsideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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